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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,095	09/18/2003	Robert P. Hammer	Hammer 0212.1	6953

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PATENT DEPARTMENT
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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,095	HAMMER ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-18,20,21 and 51-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8,20,21,51-53 and 55* is/are rejected.

7)☒ Claim(s) *4,9-18 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2006 has been entered.

2. Claims 53 and 54 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

Instant claims 1, 4, 7-18, 20, 21, 51, 52, and 55 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose all of the generic formulas recited in instant claims 1 and 51; does not disclose the additional functionalities of instant claim 1, part (d); does not disclose the size limitations of instant claim 1, part (e); does not disclose compounds corresponding to SEQ ID NOS:5, 6, and 7; does not disclose aggregation-inducing sequences corresponding to SEQ ID NOS:9-16 or Q_m where m is an integer from 25 to 45; and does not disclose combining the compounds with a pharmaceutically acceptable carrier in general. Note that unless a claim is limited exclusively to subject matter disclosed in a priority application, the claim is not entitled to the benefit of the filing date of the priority application. See MPEP 201.11(I) and (VI).

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 7, 8, 20, 51, 52, and 55 are rejected under 35 U.S.C. 102(b) and claim 53 is rejected under 35 U.S.C. 102(a) as being anticipated by the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001). The Fu et al article teaches Applicants' elected peptide, Lys-Digb-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2. See page 239, column 1. This peptide corresponds to, e.g., the fifth peptidyl sequence of claim 1 and the first peptidyl sequence of claim 53 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, and $(S)_n$ is Dpg-Lys_6-NH_2 where n=7. Note that Applicants' definition of $(S)_n$ states that the hydrophilic region comprises hydrophilic amino acids or other hydrophilic groups, i.e. can comprise non-hydrophilic amino acids and groups as long as the region as a whole is hydrophilic. This peptide also corresponds to, e.g., the first peptidyl sequence of claim 1 wherein the N-terminal end comprises Lys-Digb that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, X_{aa1} is Val, Y_{AA1} is Dbzg, X_{aa2} is Phe, Y_{AA2} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6. This peptide also corresponds to, e.g., the second peptidyl sequence of claim 53 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, n=0, and the C-terminal end comprises an additional functionality (i.e. Dpg-Lys_6-NH_2) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality.

5. Claims 1, 7, 8, 20, 21, 51, 52, and 55 are rejected under 35 U.S.C. 102(a) as being anticipated by the Fu dissertation (Louisiana State University, December 2002). The Fu dissertation teaches the peptide AMY-3 at page 126 which comprises the same peptidyl

sequences recited in instant claim 1. For example, AMY-3 of the Fu dissertation corresponds to the seventh peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, and (S) is Lys and n=7. Alternatively, AMY-3 corresponds to the tenth peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, X_{aa3} is Lys, (S) is Lys, and n=6. In view of the similarity in structure between the peptide of the Fu dissertation and Applicants' claimed peptidyl sequences, the peptide of the dissertation inherently will be capable of inhibiting the toxicity of an amyloid protein or amyloid peptide to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present the peptide of the Fu dissertation and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the peptides of the Fu dissertation. Note that patentability is not imparted to product claims merely upon the employment of descriptive language not chosen by the prior art. In re Skoner, 186 USPQ 80, 82 (CCPA 1975). The discovery of a new property or use for a previously known compound can not impart patentability to claims drawn to the compound. In re Schoenwald, 22 USPQ2d 1671 (CAFC 1992). The Fu dissertation also teaches the peptide AMY-1, which corresponds to Applicants' elected SEQ ID NO:4 and which is combined with a phosphate-buffered aqueous solution. See pages 103 and 108. The AMY-1 peptide corresponds to, e.g., the fifth peptidyl sequence of claim 1 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, and $(S)_n$ is Dpg-Lys_6-NH_2 where n=7. Note that Applicants' definition of $(S)_n$ states that the hydrophilic region comprises hydrophilic amino acids or other hydrophilic groups, i.e. can comprise non-hydrophilic amino acids and groups as long as the region as a whole is hydrophilic. This peptide also corresponds to, e.g., the first peptidyl sequence of claim 1

wherein the N-terminal end comprises Lys-Digb that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, X_{aa1} is Val, Y_{AA1} is Dbzg, X_{aa2} is Phe, Y_{AA2} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6.

6. Claims 1, 7, 8, 20, 21, 51, 52, and 55 are rejected under 35 U.S.C. 102(a) as being anticipated by the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003. The Aucoin oral presentation, as evidenced by the presentation notes supplied in the Information Disclosure Statement filed September 18, 2003, disclosed peptides AMY-1 and AMY-3 which correspond to Applicants' claimed compounds of SEQ ID NOS:4 and 6, respectively. The peptides are combined with a phosphate-buffered aqueous solution, which corresponds to Applicants' pharmaceutically acceptable carrier.

AMY-3 corresponds to the seventh peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, and (S) is Lys and n=7. Alternatively, AMY-3 corresponds to the tenth peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, X_{aa3} is Lys, (S) is Lys, and n=6. AMY-1 corresponds to, e.g., the fifth peptidyl sequence of claim 1 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, and $(S)_n$ is Dpg-Lys_6-NH_2 where n=7. Note that Applicants' definition of $(S)_n$ states that the hydrophilic region comprises hydrophilic amino acids or other hydrophilic groups, i.e. can comprise non-hydrophilic amino acids and groups as long as the region as a whole is hydrophilic. This peptide also corresponds to, e.g., the first peptidyl sequence of claim 1 wherein the N-terminal end comprises Lys-Digb that does not adversely

affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, X_{aa1} is Val, Y_{AA1} is Dbzg, X_{aa2} is Phe, Y_{AA2} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6.

The Aucoin oral presentation satisfies the requirement of 35 U.S.C. 102(a) that an invention be "known... by others in this country" because the identity of the presenter is different than the inventorship of the instant application, and any difference in authorship/inventorship satisfies the statutory requirement of "by another". See MPEP 2132(III). See also Ecolochem Inc. v. Southern California Edison, 56 USPQ2d 1065, 1071 (CAFC 2002), where the court acknowledges that oral presentations can satisfy the requirements of 35 U.S.C. 102(a). This rejection could be overcome, e.g., by the submission of a declaration under 37 CFR 1.132 showing that the subject matter of the presentation was derived from the instant inventors and was therefore not "by another". See MPEP 715.01(c), 716.10, and 2136.05.

Note that the Aucoin oral presentation is not considered to be a printed publication because insufficient evidence is of record as to whether printed copies, slides, etc. of oral presentation were made available and/or whether members of the public had time to make copies of the disclosed subject matter. Compare In re Klopfenstein, 72 USPQ2d 1117 (CAFC 2004).

7. Applicant's arguments filed June 27, 2006 have been fully considered but they are not persuasive.

It should be noted that given the breadth of the definitions of the peptidyl sequences recited in claim 1 and of their individual substituents, the claimed peptidyl sequences overlap one another in scope. Any one peptide can correspond to one or more of the claimed peptidyl

sequences as illustrated, e.g., the above revised rejections over the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001) and the Fu dissertation.

With respect to the rejection of claim 53 over the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001), page 6 of Applicants' Remarks and Arguments discusses how a declaration under 37 CFR 1.131 can be used to overcome rejections of species claims and of generic claims encompassing the species. However, the affidavit by Hammer filed December 23, 2005 is not an affidavit under 37 CFR 1.131. For example, the affidavit by Hammer is not signed by all of the inventors of the subject matter claimed; does not contain evidence of priority of invention; does not allege conception or reduction to practice prior to the publication date of the Fu et al article; and does not allege that the acts relied upon to establish priority were carried out in this country or a NAFTA country or a WTO member country. See MPEP 715.04(I); 715.07; and 715.07(c). Affidavits/declarations demonstrating that a prior art disclosure is not "by another" are considered to be affidavits/declarations under 37 CFR 1.132. See MPEP 715.01, 715.01(a), and 715.01(c)(I). Because the affidavit by Hammer does not satisfy the requirements of 37 CFR 1.131, the procedures and rules discussed by Applicants in their Remarks and Arguments are not applicable.

The rejection over the Fu et al article (J. Org. Chem., Vol. 66, pages 7118-7124) is overcome by the amendments to Applicants' claims.

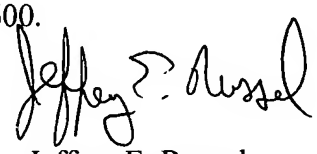
The rejection over the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003, is maintained. Applicants contend that the Hammer affidavit shows that the sequence and synthesis of peptides AMY-1 and AMY-3 was conceived by Drs. Hammer, McLaughlin, Fu, and

Miller. However, all six of the instant inventors are presumed to be the inventors of the subject matter of the rejected claims, absent evidence to the contrary. Accordingly, the peptides AMY-1 and AMY-3, disclosed by the Aucoin oral presentation and which the affidavit states was invented by Inventors Hammer, McLaughlin, Fu, and Miller, is still "by another" and remains available as prior art under 35 U.S.C. 102(a).

8. Claims 4, 9-18, and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel
July 31, 2006